K102654

510(k) Summary

Submitter Name: Vertex Dental B.V.
Submitter Address:

Phone Number: 603 369 3550
Fax Number: 603 369 3562

DEC - 3 2010

Contact Person: William Greenrose

Date Prepared: August 9, 2010

Device Trade Name: Vertex Rapid Simplified

Common Name: Denture base material

Classification Name, Number & Product Code: resin, denture, relining, repairing, rebasing
872.3760
EBI

Predicate Devices: Probase Hot (K913655), Major.Base 20 (K081884)

Device Description and Statement of Intended Use

Device Description: The Vertex hot-curing denture base material is a conventional dough pack heat cured denture base material that consists of polymethyl methacrylate powder with a heat cure monomer consisting of methyl methacrylate. This material complies with the requirements of ISO 1567, Dentistry. Denture base polymers.
The pressing technique is the processing method for Vertex hot-curing denture base material. This cadmium-free acrylic has a rapid 20 minutes polymerization cycle (overnight polymerization is also possible). The Vertex hot-curing denture base powder is available in 10 shades.

Intended Use:
The Vertex Rapid Simplified is indicated for:
1. Fabrication of full dentures
2. Fabrication of partial dentures

Summary of Technological Characteristics	All of the components found in Vertex™ hot-curing denture base materials have been used in legally marketed devices and were found safe for dental use.
Substantial Equivalence	The Vertex hot-curing denture base material is substantially equivalent to the Probase Hot (K913655) and Major.Base 20 (K081884), with respect to mode of action and intended use. It is substantially equivalent to the Probase Cold (K913655) and Major.Base 20 (K081884) denture base materials, with respect to material of composition. The submitted device pose the same types of questions about safety or effectiveness as the existing device.
Conclusion	The information discussed above demonstrates that the Vertex hot-curing denture base material is substantially equivalent to the predicate devices.
Declarations	o This summary includes only information that is also covered in the body of the 510(k). o This summary does not contain any puffery or unsubstantiated labeling claims. o This summary does not contain any raw data, i.e., contains only summary data. o This summary does not contain any trade secret or confidential commercial information. o This summary does not contain any patient identification information.

Summary of Technical Characteristics

Feature	Vertex hot-curing denture base material	Probase Hot	Major Base 20
510(k) Number	Not yet assigned	K913655	K081884
Manufacturer	Vertex Dental B.V.	Ivoclar North America, Inc.	Major Prodotti Dentari S.p.a
Classification # & Product Code	872.3760 EBI	872.3760 EBI	872.3760 EBI
Indications for Use	The Vertex Rapid Simplified is indicated for: 3. Fabrication of full dentures 4. Fabrication of partial dentures	Partial and combination dentures, conventional or implant supported Complete dentures Hybrid dentures Relines of conventional or implant dentures	Major.Base 20 is a denture base polymer for dental prosthesis. Poly-methylmethacrylate based. Heat-processed polymer. Powder and liquid. It is used for: Dental prosthesis Partial prosthesis Clasp prosthesis
Composition of Materials	**Powder:** Polymethyl methacrylate, Benzoyl peroxide, Pigments **Liquid:** Methyl methacrylate, Ethyleneglycol dimethacrylate, N,N-dimethyl-4-toluidine, Tinuvin P	**Powder:** Polymethyl methacrylate, softening agent, benzoyl peroxide, pigments **Liquid:** Methyl methacrylate, dimethacrylate (linking agent), catalyst	**Powder:** Poly-methylmethacrylate, Pigments **Liquid:** Methyl methacrylate, Ethyleneglycol dimethacrylate, N,N-dimethyl-p-toluidine, Benzophenone-3
Physical Properties	**Charpy impact strength:** 11.3 kj/m^2 **flexural strength:** 85 MPa **flexural modulus:** 2367 MPa **water absorption:** 22.5 µg/mm^3 **water solubility:** 0.11 µg/mm^3 **Residual monomer:** 1.33 ± 0.16%	**Charpy impact strength:** 1.36 kj/m^2 ± 0.09 **flexural strength** 87.4 ± 8.9 (MPa) **flexural modulus** 2904.9 ± 281.4 (MPa) **Residual monomer:** <2.2%	**Charpy impact strength:** 1.36 kj/m^2 ± 0.03 **flexural strength:** 78 MPa **flexural modulus:** 2390 MPa **water absorption:** 22.0 µg/mm^3 **water solubility:** 1.5 µg/mm^3 **Residual monomer:** 1.8%
Standards of Conformity	ISO 1567 ISO 20795 ISO 179-1 ISO 7405 ASTM F 895-84	ISO 1567	ISO 1567

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Vertex Dental B.V.
C/O Mr. William Greenrose
Regulatory Consultant
Qserve America, Incorporated
22 River Road
Claremont, New Hampshire 03743

DEC - 3 2010

Re: K102654
Trade/Device Name: Vertex™ Rapid Simplified
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Code: EBI
Dated: September 13, 2010
Received: September 14, 2010

Dear Mr. Greenrose:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

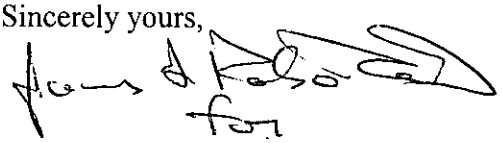
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102654

Device Name: Vertex™ Rapid Simplified

Indications For Use:

The Vertex Rapid Simplified is indicated for:
1. Fabrication of full dentures
2. Fabrication of partial dentures

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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